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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/366,081 | 08/02/1999 | SYDNEY BRENNER | 802-04RE | 2643 |
| 22918 | 7590 | 04/08/2004 | EXAMINER | |
| | | | LACOURCIERE, KAREN A | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1635 | | 24 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/366,081 | BRENNER, SYDNEY | |
| | Examiner Karen A. Lacourciere | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6, 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 and 8-13 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08-02-1999 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Reissue Applications

Receipt of the original ribbon copy of the patent, as required under 37 CFR 1.178, is acknowledged.

Specification

A substitute specification including the claims is required because the specification is not a permanent copy. Reference is made to the specification and originally issued claims, which were provided as a copy taped to the submitted pages, which is not a permanent record. Additionally, throughout the filed specification, holes punched in the specification have removed text in the specification. Applicant is directed to MPEP 1411 and 37 CFR 1.173 for the requirements for the specification of a Reissue Application. All amendments to the specification must be made in accordance with 37 CFR 1.173 (b)(1), see MPEP 1453.

Drawings

New corrected drawings are required in this application because the patent number present on the drawing must be deleted, as required by the Draftsperson's drawing review mailed with the Office Action mailed April 25, 2000. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Nucleotide and/or Amino Acid Sequence Disclosure

Clarification for the support of the sequence related amendments filed with the response of June 25, 2002 is appreciated and overcomes the grounds of the Notice of Non-responsive Amendment mailed 05-22-2002. The written form of the sequence listing submitted on June 25, 2002 provides sequences for SEQ ID NO: 9, 10 and 17 that match the sequences labeled as such in the specification and support for these sequences is found in the original specification as detailed by Applicant in the response filed June 25, 2002, however, the format of the proposed amendments to the specification, correcting the sequence information are not proper for a Reissue Application, as they do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. The amendment, therefore, will not be entered. A supplemental paper correctly amending the reissue application is required if applicant remains intent upon making a change to the sequences.

Specifically any changes relative to the patent being reissued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application, must include the following markings:

- (1) The matter to be omitted by reissue must be enclosed in brackets; and
- (2) The matter to be added by reissue must be underlined, except for amendments submitted on compact discs (§ 1.96 and 1.821(c)). Matter added by reissue on compact discs must be preceded with “ <U> ” and end with “ </U> ” to properly identify the material being added.

All amendments must be made relative to the patent specification, including the claims, and drawings, which are in effect as of the date of filing of the reissue application.

The proposed amendment to the sequence listing is of a new version of the PatentIn program which changed the format titles and font relative to the older PatentIn program version as issued. Thus, the sequence listing does not indicate the changes to the sequence listing relative to the patent specification sequence listing, as required by 37 CFR 1.173(b).

For these reasons, the amendment filed 06-25-2002 requesting the substitute pages of the sequence listing has been not entered. If applicants remain intent upon changing the sequence listing, the following steps must be taken to ensure that the amendments comply with 37 CFR 1.73(b). (a) Using the old computer readable format of the sequence listing, make an electronic copy of the sequence listing, showing the new sequence listing, as clean copy, without brackets or underlines. This electronic copy will be entered into our computer database. If applicants no longer have a copy of the old computer readable program, please contact:

Lisa Hobbs, PatentIn Search and Information Resources Administration US
Patent and Trademark Office Crystal Park 3, Suite 702, Room 750
voice: (703) 308-6573 fax: (703) 305-3014

to receive a copy of the old computer readable program. (b). Print out a clean paper copy of the disk in part (a), without brackets and underlines, for the required paper copy.
(c) Submit a statement saying that the paper copy and computer readable form are

identical and contain no new matter. (d). For all changes to the sequence listing, prepare a red marked up version to show how the sequences were changed relative to those on file. This copy is provided for the examiner's reference and to complete the file. (e). For the all sequence changes, prepare amendments to the specification in which the changed sequence is presented in a format wherein the changes are all underlined.

Reissue Applications

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,654,413 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The reissue oath/declaration filed with this application is defective because it fails to properly identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

It is noted that the declaration filed May 17, 2000 there is an inoperative or invalid statement directed to the nature of the basis for the reexamination, however, the error identified is described in general terms. A specific error is not identified and the statement does not provide a link between the error and a claim as issued or added or amended and, therefore, is not proper, as required in 37 CFR 1.175(a)(1).

Therefore, the statement set forth in the declaration filed May 17, 2000, is not considered to be sufficient to fulfill the requirements of 37 CFR 1.175(a)(1) and MPEP § 1414.

Claims 1-6 and 8-13 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Claims 10-13 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d

1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In Paper No 7, mailed 3/19/96 during the prosecution of the prior patent in US Patent Application SN 08/484,712, the Examiner states that the nearest prior art does not provide motivation or suggest increasing the minimum number of mismatches between a given tag and incorrect tag complements to at least two mismatches, i.e. subunits chosen from a minimal cross-hybridizing set as defined in the specification nor using these tags to sort polynucleotides. New claim 10 of the instant reissue application does not require this limitation because new claim 10 discusses longer oligonucleotides differing from one another by at least two nucleotides, which is broader scope than in the issued patent, wherein the complementary oligonucleotide tags require that each 3-6 nucleotide subunit of the set has at least two mismatches relative to any other subunit of the set. Additionally, claim 11 allows for the "complements to form perfectly matched duplexes", which would seem to suggest that there are no mismatches and would not require at least two mismatches in each 3-6 nucleotide subunit relative any other

subunit, which also broadens the scope of the claimed subject matter to include subject matter surrendered during the prosecution of the issued patent. Claims 10-13, therefore, are broader in scope than claim 1 and do not contain the specific element the Examiner said was necessary to be free of the prior art.

Response to Amendment

Throughout the prosecution of the instant Reissue Application, Applicant has submitted amendments to the claims that are not in the proper format for Reissue Applications, which should reflect all amendments relative to the issued claims, not the changes relative to the prior pending claims. See MPEP 1453 for proper format for filing amendments in a Reissue Application. Given the extensive prosecution history of the instant case, the claims pending will be examined in their improper format, however, Applicant must submit these amended claims in the proper format, or present newly amended claims in the proper format, in response to this Office action in order for the response to be considered fully responsive.

Additionally, it is required that Applicant provide a courtesy copy of the claims in a format wherein the claims are marked up relative to the prior pending version of the claims to facilitate the examination process.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed January 8, 2002 adds the limitation "a thousand or more" to claim 5. Applicant points to column 3, lines 2-5; column 14, lines 38-39 and column 21, lines 56-58 of the originally filed specification to support this newly added limitation. Support for this limitation could not be found in the passages Applicant indicates support this limitation. For example, Column 3, lines 2-5 indicate "many thousands of fragments", and does not provide for, for example, the lower range of a number of fragments of a thousand or more, but less than many thousands. Similarly, column 14 provides for "on the order of thousands or more" and column 21 provides for "many thousands of fragments", neither of which support the lower range of a thousand or more. Further, support for the limitation "a thousand or more" could not be found anywhere else in the originally filed specification or claims and, therefore, is considered to be new matter.

Claims 5, 6, 8 and 9 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows:

The amendment filed January 8, 2002 adds the limitation "a thousand or more" to claim 5. Applicant points to column 3, lines 2-5; column 14, lines 38-39 and column 21,

lines 56-58 of the specification of the prior patent to support this newly added limitation. Support for this limitation could not be found in the passages Applicant indicates support this limitation. For example, Column 3, lines 2-5 indicate "many thousands of fragments", and does not provide for, for example, the lower range of a number of fragments of a thousand or more, but less than many thousands. Similarly, column 14 provides for "on the order of thousands or more" and column 21 provides for "many thousands of fragments", neither of which support the lower range of a thousand or more. Further, support for the limitation "a thousand or more" could not be found anywhere else in the specification or claims of the prior patent and, therefore, is considered to be new matter.

Claim Rejections - 35 USC § 102

The rejection of record of claim 5 as anticipated by Wang et al. (mailed 04-09-2001) is withdrawn in response to Applicant's amendments filed 01-08-2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 6 and 8 are maintained as rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (EP 0 304 845) in view of Hornes et al. (US Patent 5,512,439), for the reasons of record set forth in the prior Office action, mailed 04-09-01.

Response to Arguments

Applicant's arguments filed January 8, 2001 have been fully considered but they are not persuasive. In response to the rejection of record of claims 5, 6 and 8 under 35 USC 103(a) as obvious over Wang et al. in view of Hornes et al., Applicant argues that the cited references do not supply all of the limitations of the claimed invention, specifically that neither Wang et al. or Hornes et al. teach wherein the different polynucleotides number a thousand or more. This is not found to be persuasive because Hornes et al. does teach wherein "each magnetic particle carries 10^3 - 10^6 probes", as discussed in the rejection of record. Applicant argues that the examples presented in Hornes et al. in columns 5-11 provide applications for their disclosed

particle population has a single polynucleotide attached and, therefore, does not describe particles wherein substantially all different polynucleotides in a plurality of a thousand or more different polynucleotides are attached to different microparticles.

This is not found to be persuasive because Hornes et al. is not relied upon to teach the invention claimed, as a whole, but is relied upon to teach the advantages of attaching a plurality of oligonucleotides, numbering 10^3 - 10^6 , to microbeads. Although the applications taught by Hornes et al. in column 12 may be directed to situations wherein a single oligonucleotide is attached to microparticles Hornes et al. is not limited to such examples. Wang et al. is relied upon to teach applications wherein different probes are attached to microparticles. Wang et al. does not explicitly disclose the number of a thousand or more polynucleotides, as claimed, however, the applications taught by Wang et al. are directed to multiple, different sequences, including applications wherein it would be advantageous to have a thousand or more probes and Hornes et al. teaches the advantages of attaching a number of probes greater than a thousand or more, to different particles. Therefore, all of the limitations of the claimed invention are taught by the cited references and, as discussed in the rejection of record, there is motivation to combine these teachings and a reasonable expectation to successfully make the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
December 1, 2003

Karen Lacourciere
KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER